

Notice of Allowability**Application No.**

09/486,904

Applicant(s)

SNYDER ET AL.

Examiner

CATHY K. WORLEY

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Appeal brief filed on Mar. 14, 2011.
2. ☒ The allowed claim(s) is/are 9, 20-23, 25, and 26; renumbered as claims 1-7, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 1529.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/CATHY K WORLEY/
Primary Examiner, Art Unit 1638

EXAMINER'S COMMENT

1) The Appeal Brief filed on Mar. 14, 2011, is acknowledged. After further consideration, the rejections of record are withdrawn; see reasons for allowance, below.

2) The claim amendments filed on June 27, 2003, are the most recent claim amendments; therefore, claims 9-14 and 20-25 are pending in the instant application with claims 10-14 withdrawn (see claims from June 16, 2003). The claims are amended by Examiner's amendment, below.

EXAMINER'S AMENDMENT

3) An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert N. Sahr (Registration No. 65,507) on May 11, 2011.

- 4) The application has been amended as follows:

IN THE CLAIMS:

1-8. (Canceled)

9. (Currently Amended) A method for producing a compound, said method comprising the steps of

producing a fertile transgenic plant by introducing into plant cells a DNA construct comprising a promoter, a blocking sequence, and a coding sequence of a structural gene coding for a compound that is detrimental to the plant and is commercially valuable, said blocking sequence being flanked by a pair of directly repeated site-specific recombination sequences and wherein the ~~structural gene~~ coding sequence is operably linked to the promoter only after the removal of said blocking sequence, and culturing the plant cells to produce the fertile transgenic plant;

self-pollinating said transgenic plant to produce transgenic plants that are homozygous for the DNA construct;

crossing said transgenic plant homozygous for the DNA construct with a plant having a DNA sequence comprising a coding region encoding a site-specific

recombinase that recognizes said site-specific recombination sequences to produce an F1 plant or seed:

expressing the site-specific recombinase in the F1 plant or seed;

expressing the compound; and

extracting the compound in economical quantities.

10-19. (Canceled)

20. (Previously Presented) The method of claim 9 wherein the step of crossing said homozygous transgenic plant with a plant having a DNA sequence comprising a coding region encoding a site-specific recombinase produces an F1 plant or seed that expresses the biologically detrimental compound.

21. (Currently Amended) The method of claim 20, wherein the extracting step comprises extracting the compound from leaves of the plant or seed.

22. (Previously Presented) The method of claim 9 wherein the promoter is a constitutive promoter.

23. (Previously Presented) The method of claim 9 wherein the pair of directly repeated site-specific recombination sequences are FRT recombination sequences,

and the coding region encoding the site-specific recombinase encodes the FLP recombinase and is operably linked to a constitutive promoter.

24. (Canceled)

25. (Previously Presented) The method of claim 9 wherein the promoter of the DNA construct is a leaf-specific promoter and the extracting step includes extracting the compound from the leaves.

26. (New) The method of claim 9 wherein the promoter of the DNA construct is a seed-specific promoter and the extracting step includes extracting the compound from the seeds.

Allowable Subject Matter

5) Claims 9, 20-23, 25, and 26 are allowed and are renumbered as claims 1-7, respectively.

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

6) The following is an examiner's statement of reasons for allowance:

With regard to the rejections of record from the final rejection that was mailed on Sept. 23, 2003:

- the rejections under 35 USC,112 2nd. for the recitation of "gene" and "structural gene" are withdrawn in light of the amendments to the claims that include recitations of "coding sequence" and "coding region";
- after further consideration, the rejection under 35 USC,112 2nd. for the recitation of "economical quantities" is withdrawn, because "economical quantities" is broadly interpreted to encompass any detectable amount of extracted compound;
- the rejection under 112 1st for lack of enablement is withdrawn after further consideration, because a compound that is "detrimental" as claimed is not necessarily lethal (i.e. the Examiner interprets "detrimental" broadly to be inclusive of anything that reduces the growth or vigor of the plant; and this could even be due to the production of the compound being a drain on carbon and/or nitrogen availability which slows the growth of the plant via source/sink issues), therefore, the rationale for the lack of enablement that is based on lethality is improper; and

- the obviousness rejection under 35 USC 103 is withdrawn because none of the references cited teach or suggest extraction of the compound, therefore, this limitation is not covered by the references of record.

The reference by Odell et al appears to teach the same recombinase system as the system claimed in the instant claims; however, the method the system is being utilized in is a method for making seedless plants by expression of barnase. There is no motivation or rationale for one to extract barnase from the plant, because the utility of barnase is the effect it has *in planta*, and there is no known or accepted utility for extracted barnase. After perusing the literature that was available in 1997, it does not appear that one of ordinary skill in the art would have thought to utilize this system in a method that utilizes the plant as a bio-reactor for the production of a compound that is to be extracted from the plant.

7) Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is

(571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CATHY K WORLEY/
Primary Examiner, Art Unit 1638